



9430 Key West Avenue, Suite 150
Rockville, MD 20850

VACANCY ANNOUNCEMENT

Director, Biologics Manufacturing & Process Engineering

Position Summary: Responsible for process development and manufacturing activities at Therabron. The Director of Manufacturing will oversee process development, analytical method development, and implementation of cGMP process at a selected CMO, including tech transfer, process validation, analytical testing, and completion of cGMP production campaigns (microbial fermentation). This person will be viewed as the subject matter expert in these areas. He/she will play an important role in the overall execution of the company's business plans as well as assist in helping grow the business.

Duties and Responsibilities include the following (other duties may be assigned):

- Develop manufacturing strategies for products in collaboration with Company Executives
- Acquire a thorough working knowledge of existing processes and analytical methods
- Improve upstream and downstream process development for lead biologic candidate, including hands-on work in lab
- Supervise small process development team
- Design, develop, and manage upstream and downstream process development for new biologic product candidates in collaboration with existing staff
- Design and develop analytical methods for in-process, intermediates testing, final specification testing, and stability testing in collaboration with existing staff
- Support development of tech transfer package and selection of CMO
- Manage tech transfer to CMO and oversee process scale-up, GMP production, and process validation
- Prepare written process and data summaries, contribute to development of batch production records, SOPs, test records, and draft sections of regulatory CMC submissions

Qualifications:

- MS required (Ph.D. preferred); degree in biochemistry, chemical engineering, or similar discipline with a minimum of 7 years of hands-on bioprocess experience in the Biotechnology / Biopharmaceutical industry. Minimum of 4 years cGMP recombinant protein manufacturing experience (microbial products preferred).
- Strong protein purification and analytical background
- Experience working with quality control systems, and designing/writing batch production records, SOPs, test records, data summaries, etc.
- Solid working knowledge of FDA and ICH guidelines for GMP, analytical method validation, process validation, etc.
- Experience contributing to regulatory CMC submissions
- Experience with biologics formulation studies preferred
- Track record of successful bioprocess development and technology transfer from bench through commercial scale with biologics produced through microbial fermentation and experience with management of Contract Manufacturing Organizations strongly preferred.

- Strong leadership, relationship management, and organizational planning and project management skills, in addition to technical knowledge. Ability to influence sites, suppliers and colleagues into adopting "best practices".
- Strong process equipment operational theory and troubleshooting skills.
- Excellent communication skills – technical writing skills; verbal, listening and interpersonal with the ability to transfer knowledge to others.
- Experience supervising others
- Willingness to take on challenges of a small company environment

This position is based in Rockville, MD and requires a highly organized, detail-oriented, self-starter who possesses the ability to work effectively while engaging multiple challenges. This position requires broad hands-on experience and knowledge to solve operational and technical challenges associated with the transition from bench to clinical to commercial scale biologics manufacturing. The ideal candidate will be highly motivated, have superior communication and organizational skills, a high level of discipline and can work well both independently and in a team environment. We will prioritize a candidate that management believes can grow with the company.